AHRQ Update

Setting a Research Agenda for Medical Errors and Patient Safety

Gregg Meyer, Nancy Foster, Shana Christrup, and John Eisenberg

Although medical errors and patient safety have been the subject of research for more than a decade, with much of the research supported by the Agency for Healthcare Research and Quality (AHRQ) and its predecessor organizations, the number of researchers involved—and the scope of the research—has been relatively limited.

Beginning with studies of anesthesia errors, prescription drug errors, and surgical errors, researchers have sketched the outline of an epidemiology of medical errors and developed a rudimentary taxonomy of errors. These studies suggest that as many as one of every 25 hospital patients may be injured by a medical error, and an estimated 48,000 to 98,000 hospital patients die from such errors each year. In contrast, little is known about medical errors in ambulatory care settings, nursing homes, hospice care, and mental health facilities (in- or outpatient). In addition, little is known about errors that are not detectable through the medical record.

AHRQ-supported research (Leape, Brennan, Laird, et al. 1991) has shown that just one type of error—preventable adverse drug events—caused one out of five injuries or deaths per year to patients in the hospitals that were studied. Other AHRQ-funded research (Leape, Bates, Cullen, et al. 1995; Kovner and Gergen 1998) has pointed out the role of systems failures in the etiology of medical errors.

Although dramatic cases of errors have surfaced in the news, the issue of medical errors did not catch the attention of policymakers and the public strongly until the release of the Institute of Medicine's (IOM) report on medical errors, *To Err is Human: Building a Safer Health Care System* (IOM 1999). In response to this report, President Clinton asked the Quality Interagency

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Coordination (QuIC)[1] Task Force—a group that consists of federal agencies involved in delivering, purchasing, regulating, or studying health care—to draft a response that outlines the federal government's existing programs and plans to address the issues of medical errors and patient safety. That report identifies over 100 specific federal action items in response to the IOM report.

Among the actions proposed in the QuIC's response, *Doing What Counts for Patient Safety: Federal Actions to Reduce Medical Errors and Their Impact* (QuIC Task Force 2000), was the National Summit on Medical Errors and Patient Safety Research. This one-day meeting was held in Washington, DC on September 11, 2000 to solicit responses from the users of patient safety research about their pressing needs and to highlight specific research questions related to those needs.

During the Summit, 24 users of medical errors and patient safety research (Table 1, section A) were invited to testify orally about their research questions, and about 35 other users submitted detailed written testimony (available on the QuIC web site, *http://www.quic.gov*). Many of those testifying or submitting written testimony represented leading professional organizations, patient advocacy groups, institutional providers, accreditors, health care purchasers, and policymakers. Each of the groups was asked the same focused question: "What is the research that you could put into practice to improve patient safety?" As a result of that focused discussion, the research questions identified comprise a "user-driven" research agenda.

To ensure that the users' input led to a coordinated private–public action plan by funders of patient safety research, representatives from 14 public- and private-sector organizations that fund patient safety research (Table 1, section B) were invited to listen to the oral statements on September 11 and to read the written testimony. A number of these organizations provided financial cosponsorship for the Summit. About two weeks later, the funding-organization representatives met to develop an integrated, coordinated, user-driven, patient-focused, system-based patient safety research agenda for all 14 organizations. In organizing the research issues that are the most important to create the safest possible healthcare system, the timing of the various research objectives could serve as a logical structure. Therefore, each of the specific research aims (Table 2) was separated into one of three categories: short- (six months to two years), medium- (just over two years to five years), and long-term (over five years). The research aims were broadly categorized as addressing the epidemiology of errors, the infrastructure to improve patient safety, safety-related information systems, knowing which interventions should be

Table 1: Invited Witnesses and Panelists, National Summit on Medical Errors and Patient Safety Research, Washington, DC, September 2000

A. Invited witnesses

Name	*Affiliation*
Susan E. Sheridan	Consumer, Boise, ID
Robert F. Meenan	The Arthritis Foundation
Steve Wetzell	The Leapfrog Group
Mary Jane England	Washington Business Group on Health
Gregg Lehman	National Business Coalition on Health
Gordon Sprenger	American Hospital Association
Saul N. Weingart	Harvard Executive Session on Medical Error and Patient Safety
Robert M. Crane	Kaiser Permanente
Dale Bratzler	American Health Quality Association
David Woods	Human Factors and Ergonomics Society
Robert Wears	MedTeams Consortium
Michael Cohen	Institute for Safe Medication Practices
Patricia Underwood	American Nurses Association
Mark E. Bruley	ECRI—Accident and Forensic Investigation
Joanne Lynn	Americans for Better Care of the Dying/Center to Improve Care of the Dying (RAND)
Lucy A. Savitz	University of North Carolina, Chapel Hill
N. Stephen Ober	Synergy Health Care, Inc.
Marie Dotseth	Minnesota Department of Health
Timothy T. Flaherty	American Medical Assocation Board of Trustees
Roger M. Macklis	American Medical Group Association
Jim Winn	Federation of State Medical Boards of the United States, Inc.
Paul M. Schyve	Joint Commission on the Accreditation of Healthcare Organizations
Sharon Martin	Texas Forum on Health

B. Organizations represented by panel members

Federal Agencies:	Department of Defense
	Department of Veterans Affairs
	Agency for Healthcare Research and Quality
	Centers for Disease Control and Prevention
	Health Care Financing Administration
Private-Sector Organizations:	Aetna U.S. Healthcare
	California HealthCare Foundation
	The Commonwealth Fund
	Grantmakers in Health
	Jewish Healthcare Foundation
	Robert Wood Johnson Foundation
	Kaiser Family Foundation
	W.K. Kellogg Foundation
	National Patient Safety Foundation
	Premier Health Care Systems, Inc.
Foreign Governments:	National Health Service, United Kingdom
	New South Wales (Australia) Council for Quality in Healthcare
	New Zealand Ministry of Health

Table 2: Preliminary Research Agenda on Medical Errors and Patient Safety, Generated by the National Summit on Medical Errors and Patient Safety Research, Washington, DC, September 2000

Short Term	*Medium Term*	*Long Term*
Epidemiology of errors • What are the barriers, opportunities, and incentives to studying errors in nonhospital settings, and what are the best strategies to address such barriers?	**Epidemiology of errors** • What are the types of errors (e.g., failure to diagnose, human/machine interaction, medication-related)? • Are there differences in the types or rates of errors in settings other than acute care? • Who are at risk for particular kinds of errors? [Suggested groups for study include patients who are terminally ill; are mentally ill; are diagnosed with chronic diseases or disabling conditions; are children (particularly newborns under 5 kg); have limited English proficiency and low health literacy; are women, low-income individuals, members of minority groups, individuals requiring end-of-life care, or urban/rural residents.] • What is the relationship of the health of workers to patient safety? • What are particular system vulnerabilities that lead to an increased occurrence of medical errors?	**Epidemiology of errors** • How do we know which outcomes are caused by error, rather than by underlying disease or disabling condition? • What human factors lead to error? • What are typical clinician-patient interaction problems? • How can human/technology interaction be made safer? • How do system complexities affect the ability to improve safety?
Infrastructure to improve patient safety • What are the proper roles for different interest groups in promoting patient safety?	**Infrastructure to improve patient safety** • What analytic capacity needs to be developed?	

- Point of care (Patients and providers who have direct interaction with each other are the initial research dyad.)
- Environment or context in which care is delivered (purchasers, legislatures, organization leaders, oversight bodies such as accreditors and boards, state programs, courts, licensure and accrediting bodies)

- How can the efforts of disparate parties involved with patient safety be coordinated?
- What should be the common vocabulary (errors, adverse events definitions, typology, data standards)?

Information systems

- What makes a reporting system successful?
- What useful data sources exist?
- What can we learn from existing systems?
- What data should be collected and how?
- Can we develop a common definition of a "reporting system" or what data is most useful for which purposes? For example, should reports primarily focus on errors, injuries, "incidents," risk factors, or safety practices? Who should submit those reports? Should it be providers, hospitals or organizations, patients, manufacturing companies, and/or administrative bodies? How should the data be collected?
- What infrastructure is needed?
- How can data be integrated?
- How can we best develop talent to perform analysis and interventions?
- How can we best develop an organizational culture of safety?

Information systems

- How does one collect information on omissions of care?
- How can data be clustered to facilitate analysis?
- How do we measure success of the reporting systems?
- In providing information to potential users, how can confidentiality and the need to inform be balanced?
- How can we best develop infrastructure to support data collection, analysis, and use?

Information systems

- How do we measure overall success of the reporting systems?
- How can more complete data be collected?

continued

Table 2: *Continued*

Short Term	*Medium Term*	*Long Term*
Should it be by compiling routinely collected surveillance data on indicators of possible errors, performing a medical record review, or conducting surveys? How should the types of errors be classified (commission, omission, severity)? • How can privacy/confidentiality be assured? • What legislation facilitates/hinders reporting? • What infrastructure is needed to support data collection, analysis, and use?		
Knowing which interventions should be adopted • What level of evidence is required? • How should the effectiveness of safety improvement efforts be measured? • How will we measure unintended consequences? • Can we catalogue evidence-based successful interventions? • How can we best get leadership and governance involved in promoting and prioritizing safety? • What can we learn from other industries?	**Knowing which interventions should be adopted** • What interventions increase safety? How should these interventions be evaluated? • What effect does training have on safety? • What technologies are effective in improving safety? • What procedural redesigns are effective in improving safety? • How can technologies, drugs, and procedures be designed and tested to improve safe use prior to general marketing? • How is simulation useful in training and premarket testing? • How do we know if interventions are realistic and applicable in routine practice environments?	**Knowing which interventions should be adopted** • What are the organizational changes or characteristics that affect safety? • How does trust among health care professionals and between professionals and patients influence the culture of safety? • What cultural, organizational, and leadership factors promote safety improvement? • What factors foster or hinder reporting? • How does an organization create a nonpunitive environment for improvement? • What is the effect of design and structure on safety?

Adoption issues
- How can we create a business case for safety in provider organizations?
- How can we determine the cost of doing the wrong thing to the wrong patient at the wrong time?
- How can we engage the public in the patient safety issue? What type of information is important to the public?

Using the information
- How can useful information be provided effectively to those who can act (e.g., consumers, providers and provider organizations, purchasers, states, and oversight organizations)?

Transition issues
- How can we collect data that follows patients across transitions in care?
- How can we best foster education of both professionals and nonprofessionals (e.g., through formal education, continuing health education, in-service training)?
- What working conditions improve or detract from patient safety (how staffing ratios, the mix of skills among staff, and work/rest cycles influence patient safety)?
- How can research on safety improvement be integrated into training promptly?

Adoption issues
- Research on adoption: Why are interventions adopted and why not?
- How can we create a business case for safety among purchasers and policymakers?
- How can we determine the cost of poor quality?

Using the information
- How can we encourage adoption and use of safety information?
- Can purchasers assist consumers in identifying risks from care?

Transition issues
- How can we foster communication among health professionals?
- What are the underlying causes of breakdowns in communication?

Adoption issues
- Why do some organizations adopt safety practices quickly while others resist the adoption? Why are certain adopted safety processes more successful in some organizations compared with others?

continued

Table 2: *Continued*

Ongoing issues
- How do various cultural issues affect patient safety?
- When is international collaboration beneficial? What can we learn from other countries who are dealing with patient safety issues?
- How can we effectively use different methodologies (qualitative and quantitative, use of narrative, syntheses) when researching patient safety questions?
- How can we maintain a patient-centered focus in research and priority setting?
- How can we move past thinking about errors and instead discuss the risks to patients and vulnerabilities of systems, which manifest themselves as mistakes?
- What is the best method for diffusion of successful approaches?
- How can we coordinate our efforts?

Mechanisms
- How can we develop a vision of a safe health care environment?
- How can we form successful partnerships between users, doers, and funders?
- How can we take advantage of natural experiments?
- How should we engage the legal community in patient safety research?
- How can we develop more research capacity?
- How can we begin to focus on underlying causes?
- What is the best method for developing tools to facilitate adoption of successful interventions, including self-assessment?
- How do we form/maintain a multidisciplinary approach to research?

adopted, the process of adopting interventions, using the information, and transition issues.

The short-term projects are those for which the users expressed their most pressing needs and address issues that are currently inhibiting their ability to move forward. Such research projects may extend past the outlined time period, but the main objective would be to begin those projects immediately. Medium-term projects may require some initial funding for planning and start-up, but the full benefit of the research results will require the use of information from some of the short-term projects. The objectives of the long-term projects will be met, in many instances, only if the results of preliminary short- and medium-term projects are used to develop the long-term research plans.

In addition, the funders identified a series of ongoing issues, including those related to mechanisms of applying research to health care, that did not fall into categories by time frame. These overarching questions will need to be kept in mind by researchers and funders regardless of the specific patient safety issues under consideration. Although each of the funding organizations may have a different focus within the overarching agenda and may prioritize its individual research agenda differently, all agreed that the overall issues for patient safety research were captured in the outlined research agenda. Given the extent of both the users' comments and those of experts in the patient safety field, the research agenda is rather broad in scope. This preliminary research agenda should encourage the development of more focused discussions on various aspects of patient safety research.

AHRQ has initiated that process by sponsoring a second one-day meeting—Patient Safety at the Clinical Interface—in the Chicago area on November 30, 2000. This meeting brought together representatives of provider organizations, from physicians and nurses to health care aides and health care administrators, to discuss how the medical errors and patient safety research agenda can best be focused to meet the needs of providers and patients. Future meetings will be scheduled to provide more detail for the current research framework that will inform future cycles of funding in patient safety.

This user-driven patient safety research agenda is not meant to capture other aspects of the patient safety issue (e.g., legislative and legal issues) that should also be addressed to allow the patient safety effort to move forward. The research agenda could help formulate proper responses to obvious policy dilemmas, but it is intended to be a part of, not the complete solution to, patient safety issues.

The panelists who participated in the development of the preliminary research agenda were in agreement that it must be viewed as a "living document." Developments in patient safety research, agenda-setting activities that focus on particular roles and issues, and additional input from stakeholders will require future revisions to this document. Nevertheless, AHRQ has begun to put this user-driven agenda into practice by referencing this agenda in all of the patient safety Requests for Applications it will be releasing in fiscal year 2001. As the agenda evolves, AHRQ will continue to use it as a touchstone to guide future investments in patient safety research, such as for the Request for Applications regarding the Centers of Excellence for Patient Safety Research and Practice program (*http://grants.nih.gov/grants/guide/rfa-files/RFA-HS-01-002.html*) and the Developmental Centers for Evaluation and Research on Patient Safety (*http://grants.nih.gov/grants/guide/rfa-files/RFA-HS-01-007.html).* By conscientiously focusing research on the needs of users, AHRQ hopes to maximize the impact on patient safety from the public's investment in research.

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NOTE

1. Visit *http://www.quic.gov* for additional information.

REFERENCES

Institute of Medicine (IOM). 1999. *To Err is Human: Building a Safer Health Care System.* Washington, DC: National Academy Press.

Kovner, C., and P. J. Gergen. 1998. "Nurse Staffing Levels and Adverse Events Following Surgery." *Image: Journal of Nursing Scholarship* 30 (4): 315–21.

Leape, L. L., T. A. Brennan, N. Laird, A. G. Lawthers, A. R. Localio, B. A. Barnes, L. Hebert, J. P. Newhouse, P. C. Weiler, and H. Hiatt. 1991. "The Nature of Adverse Events in Hospitalized Patients. Results of the Harvard Medical Practice Study—II." *New England Journal of Medicine* 324 (6): 377–84.

Leape, L. L., D. W. Bates, D. J. Cullen, J. Cooper, H. J. Demonaco, T. Gallivan, R. Hallisey, J. Ives, N. Laird, G. Laffel, R. Nemeskal, L. A. Petersen, K. Porter, D.

Servi, B. F. Shea, S. D. Small, B. J. Sweitzer, B. T. Thompson, and M. Vander Vliet for the ADE Prevention Study Group. 1995. "Systems Analysis of Adverse Drug Events." *Journal of the American Medical Association* 274 (1): 35–43.

Quality Interagency Coordination (QuIC) Task Force. 2000. *Doing What Counts for Patient Safety: Federal Actions to Reduce Medical Errors and Their Impact.* Rockville, MD: Quality Interagency Coordination Task Force.